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| 09/836,602 | 04/18/2001 | Axel R. Zander | 35-204 | 8963 |

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| EXAMINER |
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LEFFERS JR, GERALD G

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| ART UNIT | PAPER NUMBER |
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1636

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DATE MAILED: 08/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,602

Applicant(s)

ZANDER, AXEL R.

Examiner

Gerald G Leffers Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of a response filed 4/2/03 as Paper No. 16. In Paper No. 16 each of claims 1-11 was amended. A declaration (Paper No. 14) from the assignee, Vision 7 GmbH, was filed along with Paper No. 16 concerning the biological deposit (#13396 as recited in claim 6). Finally, a supplemental amendment was filed on 5/14/03 as Paper No. 17 in which several claims were amended (claims 1-5, 7-11) and in which the remaining non-elected claims were cancelled.

Claims 1-11 are pending and under consideration in the instant application. Any rejection of record in the previous office action (Paper No. 13, mailed 11/05/02) not addressed in this action is withdrawn. This action is not final due to new grounds of rejection made herein that were not necessitated by applicant's amendment of the claims in Papers No. 16 or 17.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicant's amendment of the claims in Paper No. 17.**

Each of the claims is drawn towards a gene transfer vector comprising a transgene and a nucleic acid sequence encoding a CD34 surface marker or fragment or variant of the same. Each of the claims comprises the functional limitation that the fragment or "variant" of a CD34 surface marker is identifiable by a CD34 detection method. Claims 3 and 8 recite a "mutant" of a sequence encoding CD34. Each of the rejected claims further recites the limitation that the variant or mutant is identifiable by a CD34 detection method. The CD34 protein can be from any source, or can be identified by SEQ ID NOS: 1-6.

The definition provided by the specification for a "variant" of CD34 reads on essentially any protein that shares at least some common structural or functional characteristic of CD34 (e.g. page 4, lines 20-24). The term "mutant" in the context of a CD34 surface marker is not explicitly defined by the instant specification. Thus, the rejected claims read on an extraordinarily large genus of polypeptides (i.e. mutants or variants) that must be detectable in some fashion by some CD34 detection method. The only CD34 detection methods described by the instant specification are immunologically based methods where an anti-CD34 immunoglobulin is used to specifically detect the presence of the protein.

The instant specification describes three embodiments for CD34 which are expressible as surface markers for eukaryotic cells and which are detectable by CD34 detection methods (e.g. Figure 1). The specification does not, however, teach a basis for one of skill in the art to envision modifications of the CD34 polypeptide which will remain detectable by a given CD34 detection method. Nor does the prior art appear to teach in what ways one can alter a given CD34 polypeptide and still have it remain detectable by a given CD34 detection method.

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Given the broad genus of polypeptides encompassed by the rejected claims, and given the unpredictability of envisioning alterations to a given CD34 polypeptides such that it will remain detectable by a given CD34 detection method, one of skill in the art would not have been able to envision a sufficient number of specific embodiments of the claimed invention to describe the broadly claimed genus. Therefore, one of skill in the art would have reasonably concluded applicant was not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 8 recite the limitations of a “variant” and a “mutant” of a particular CD34 coding sequences in the same claim. It is unclear the difference between a “variant” and a “mutant” of a CD34 coding sequence. **This is a new rejection.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The rejected claims are directed to a gene transfer vector which contains (i) a transgene, and (ii) a nucleic acid encoding a CD34 surface marker, or a fragment or variant of the same, wherein the surface marker or fragment or variant is detectable by a CD34 detection method. The CD34 surface marker can comprise SEQ ID NO: 2, 4 or 6, or a fragment or variant thereof. The CD34 surface marker can be encoded by SEQ ID NO: 1, 3 or 5, or by a fragment, mutant or variant of SEQ ID NO: 1, 3 or 5. There is no limitation in the claims as written that the fragment or variant or mutant of CD34 be expressible as a surface marker. The specification so broadly defines a "transgene" (e.g. page 4, first paragraph) that any gene encoding a protein that changes the physiology of the host cell in which it is produced is encompassed by the claims (e.g. a selectable drug resistance marker). The specification does not expressly define the term "gene transfer vector". Thus, a reasonably broad interpretation of the term encompasses any vector that can be transferred to a heterologous host cell. The term "variant" is so broadly defined in the instant specification (e.g. page 4, lines 20-24) as to read on any protein that shares some structural or functional characteristic of CD34 (e.g. being a cell surface protein). Likewise, the concept of a "mutant" of CD34 is not explicitly defined in the specification, so that the term can be reasonably be read to encompass any protein that shares some functional or structural characteristic of CD34. Thus, the rejected claims read on any expression vector encoding a "variant" or "mutant" of CD34 and which also comprises an additional gene that can be expressed in given host cell (i.e. the "transgene").

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Claims 1-3, 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hawley et al (U.S. Patent No. 5,962,644; applicant's citation in Paper No. 4; see the entire patent). **This is a new rejection.**

Hawley et al teach the cloning and expression of the cDNA sequence encoding the porcine CD34 protein (e.g. Figure 1; columns 7 to 8, bridging paragraphs; Examples 2-3). Hawley et al teach that human CHO cells can be used for expression of the CD34 proteins of their invention (e.g. Example 3).

Claims 1-3, 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Simmons et al (Journal of Immunology, 1992, Vol. 148, No. 1, pages 267-271; applicants citation in Paper No. 9; see the entire reference). **This is a new rejection.**

Simmons et al teach the cloning of a cDNA encoding human CD34 and expression of the cDNA in human COS cells (e.g. the Abstract).

Conclusion

Claims 1-5, 7-11 are rejected. Claim 6 is allowed.

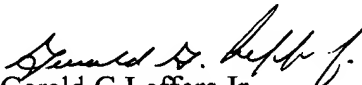
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
August 5, 2003